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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/147,052	04/05/99	SAITOH S	981167

023850 HM22/0502
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EXAMINER	
HINES,J	

ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/147,052	Saltoh et al.
Examiner	**Art Unit**
Ja-Na Hines	1645

-- Th MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 21, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-11 and 15-19* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-11 and 15-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on February 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/147,052 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. Claims 2, 5, 9-11 and 15-16 have been amended. Claim 14 has been canceled. Claims 18-19 have been added. Claims 2-11 and 15-19 are pending in the office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2-11 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth that the fusion protein comprise a polypeptide causing an antibody-antigen reactions and having a epitope and a polypeptide having a epitope of Herpesvirus outer membrane protein, therefore the written description is not commensurate in scope with the claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

A skilled artisan cannot envision the detailed structure of a polypeptide having at least one epitope of Herpesvirus outer membrane, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The claims do not recite a particular epitope. There are many known epitopes of the Mg polypeptide and Herpesvirus outer membrane protein, further there is more then one outer membrane protein of the Herpesvirus. The claims failed to specify which outer membrane protein or a particular epitope. An adequate description requires more than a mere statement that it is part of the

invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that An adequate written description of a DNA or polypeptides comprising epitopes...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

4. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 16 and 17 are directed to vaccines comprising fusion proteins as effective ingredients against subsequent infection with *Mycoplasma gallisepticum*. However, the instant specification fails to provide any experiments which show that such a vaccine would be effective in protecting against *Mycoplasma gallisepticum*. The vaccine art is highly unpredictable and the

instant specification fails to provide any information that any fusion protein comprising any epitope of *Mycoplasma gallisepticum* and any epitope of Herpesvirus outer membrane protein would provide immunity from a *Mycoplasma gallisepticum* infection. There are no immunological experiments provided to demonstrate that a person or animal immunized with any of the claimed fusion proteins would be protected from *Mycoplasma gallisepticum*. There are no protocols provided which demonstrate which fusion proteins would be effective in immunization, nor are there any protocols detailing the amount of fusion protein which is needed to mount a sufficient immune response. The specification fails to teach how to formulate and use the claimed vaccines. The specification does not provide substantive evidence that the claimed vaccines comprising fusion proteins are capable of inducing protective immunity. This demonstration is required for the skilled artisan is to be able to use the claimed vaccines for their intended purpose of preventing *Mycoplasma gallisepticum* infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem of vaccine development is the identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody

response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

The specification identifies a fusion protein comprising any epitope of *Mycoplasma gallisepticum* and any epitope of Herpesvirus outer membrane protein would provide immunity from a *Mycoplasma gallisepticum* infection. The specification fails to teach the identity of the epitopes and the make up of the polypeptides involved. Further, the specification fails to provide an adequate written description of polypeptides and entire fusion protein, the skilled artisan would be required to de novo locate, identify and characterize the claimed fusion proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to fusion proteins with the claimed characteristics.

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated fusion protein comprising SEQ ID NO:2 and 4, does not reasonably provide enablement for a fusion protein comprise a polypeptide causing an antibody-antigen reactions and having a epitope and a polypeptide having a epitope of Herpesvirus outer membrane protein which has a sequence 90% homologous to the native Herpesvirus outer membrane protein. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims

Claim 19 recites 90% homologous to the native Herpesvirus outer membrane protein, and that a variant can be obtained by deletion, substitution or insertion of one or more amino acids, however that specification provides no guidance as to what amino acids may or may not be changed without causing a detrimental effect to the polypeptide to be produced. The claim recites the a outer membrane protein with 90% identity, however does not recite which outer membrane protein it is being compared too. The claim broadly teaches 90% homology which includes substitution or insertion, therefore any amino acid is being claimed, and no specific location for where the deletion, substitution or insertion or any combination thereof is recited, if 10% of the amino acids are substituted or inserted the resulting polypeptide could result in an polypeptide not taught and enabled by the specification.

Further, it is unclear how to define the fusion protein since the metes and bounds of the polypeptides are not known. Neither the claims nor the specification teach how to obtain a polypeptide by deletion, substitution or insertion of one or more amino acids. There is no guidance as to what amino acids may or may not be changed without causing a detrimental effect to the polypeptide being claimed. The claim broadly teach polypeptides which include substitution or insertion, therefore any polypeptide is being claimed, and no specific location for where the deletion, substitution or insertion or any combination thereof is recited. Thus, the resulting polypeptide could result in a polypeptide not taught and enabled by the specification.

Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984", (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes:

1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge;

2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a Proline residue, which must distort the alpha-helix;

3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "Protein structure: A Practical Approach, 1989; pages 184-186" teaches that present day site directed mutagenesis of a gene allows any amino acid in a protein sequence to be changed to any other, as well as introducing deletions and insertions. The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

The substitution of any amino acid in any location within the polypeptide would not predictably result in a stable polypeptide. The specification does not provide guidance on how any amino acid can be substituted or inserted for the production a stable polypeptide nor does the specification provide guidance on how any location can be used to produce a stable polypeptide. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which deletions, substitutions or insertions or any combination thereof would result in the desired stable polypeptide. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino acid at any location to produce this polypeptide. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

6. Claims 2-11 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 recites a polypeptide causing an antibody-antigen reaction with *M. gallisepticum* and a Mg polypeptide showing antigenicity. Claim 18 does not reasonably provide proper basis for the use of a polypeptide causing antibody-antigen reactions or a Mg polypeptide showing antigenicity. Furthermore, neither the specification nor any of the claims disclose a polypeptide causing an antibody-antigen reaction with *M. gallisepticum*. It is unclear how to define "causing an antibody-antigen reaction." The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 is indefinite because it recites the phrase "capable of". The claim does not denote whether the fusion protein will or will not immunize. Suggested claim language for the polynucleotide which hybridize is "a fusion protein...which immunizes."

Claim Objections

8. Claims 2-11 and 15-19 are objected to because of the following informalities: In claim 18 Mg should be designated as an acronym for *M. gallisepticum*. Appropriate correction is required.

Claim 16 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependency on any of claims 2-8 and 18. See MPEP § 608.01(n). Accordingly, the claim 16 not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-10, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200). Sajto et al., (WO 94/23019) teaches novel polypeptides, DNA coding for those polypeptides, recombinant vector containing the DNA, recombinant virus prepared using the vector and various uses (title). "..The polypeptide exhibits the antigenicity of *Mycoplasma gallisepticum*, a fused polypeptide comprising the above polypeptide and connected to the N-terminus thereof, a signal membrane anchor of a type II outer-membrane polypeptide of a virus that infects birds, or a polypeptide capable of reacting with a mycoplasma-immune serum or a mycoplasma-infected serum and exhibiting a substantially pure antigenicity, respectively having amino acid sequences of about 32 kDa, about 40 kDa or about 70 kDa. The expression with a recombinant virus of a polypeptide modified to such as extent as to exhibit an antigenicity equivalent to that of any of the above polypeptides. The use of a recombinant virus as a live vaccine." (Abstract). The document also teaches that the fused polypeptide can be used as an anti-*Mycoplasma gallisepticum* (MG) infectious disease vaccine and can use the recombinant fowlpox virus (FPV) which has DNA which codes for the signal membrane anchor and can be found by analyzing the hydrophobic peptide region on the N-terminus side of the type II envelop protein in reference to an amino acid sequence. However, Sajto et al., does not specifically recite a polypeptide derived from a Herpes outer membrane protein.

Yoshida et al., (Virology 1994, vol. 200) teaches the glycoprotein B genes of Marek's Disease Virus Serotypes 2 and 3 and the identification and expression by recombinant fowlpox virus. Marek's disease is a malignant T-cell lymphoma of chickens caused by Marek's disease virus MDV), an avian herpes virus (page 484 para. 1). MDV has been classified as a gamma-herpes virus based upon its tropism, however other studies based upon its gene arrangement indicate that it is more closely related to alpha-herpes virus (page 484 para. 1). The MDV-1 homolog of the herpes simplex virus glycoproteinB (gB) has been cloned and sequenced (page 484 para .3). This gene (gB-1) encodes the B-antigen complex: gp100, gp60 and gp49 (page 484 para. 3). The gB of Herpes Simplex Virus (HSV) is the best characterized of the HSV glycoproteins and it has been shown to be essential for virus infectivity (page 484 para. 5)The gB can be one if the major target of the host immune response and in many herpes viruses, it has been reported that gB homologs are well conserved (page 484 para. 5). The recombinant fowlpox virus (FPV) have been used to express foreign genes and to evaluate their immunogenic potential (page 484 para. 6). Previous studies, show an FPV recombinant expressing the gB-1 gene to elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV (page 484-485-para, 6-1). That data suggest that FPV recombinant is a good candidate for an MDV vaccine and that gB is an important target for the host immune response (page 485 para. 1). An analysis of the predicted amino acid sequences was determined along with a 5' hydrophobic signal sequence which three of the gBps contain (page 487 para. 9). It was predicted

that the N-terminal hydrophobic region of the gB-1 could serve as a signal sequence (page 488 para .1).

Therefore it would have been obvious to use the polypeptide derived from Yoshida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Sajto et al., (WO 94/23019) because Sajto et al., teaches that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response.

Response to Arguments.

10. Applicant's arguments filed June 27, 2000 have been fully considered but they are not persuasive.

11. Claims 2-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Applicants argue that the specification details a description of polypeptides derived from herpesvirus. However the claims are indefinite. The term "derived" does not provide the character or properties from the source that are to be retained in the final product, e.g., paper is derived from wood but is very different from wood. The phrase "derived from" should be changed to "isolated from". The specification does not

teach how to make additional polypeptides derivatives nor do the claims recite what characteristics are needed to determine whether an unknown polypeptide could be considered a derivative polypeptide. The specification does not disclose a definition or limitations for any derived polypeptide, nor does the specification teach a requisite amount of retained qualities needed or characteristics necessary to determine derivative polypeptides, the specification states only that the starting material is herpesvirus.

12. Claims 9-12 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for being indefinite. Claims 9-12 recite DNA coding for the fusion protein, however no specific DNA sequence is recited. Applicant argue that "it is submitted that the DNA sequence corresponding to many such polypeptides is known, as mentioned in the specification, or can be determined by conventional methods." Therefore it is unclear if applicant are stating that the hybrid DNA as recited in the claims is already known in the art. It is recommended that applicants clarify their arguments.

However, the recitation of hybrid DNA is still unclear. There is no teaching of what specific amino acids as required in the DNA sequence to code for the fusion protein of claims 2 through 8 and 18.

13. Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Applicant argues that the specification teaches the selection of appropriate polypeptides and their function. However neither the claims nor the specification recite a specific protein size, sequence or amino acid fragment, accordingly, there is no teaching that a peptide meeting this criteria will be effective as part of a vaccine.

14. Claims 2-10, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) is maintained. Applicants argue that Sajto et al., is silent as to the membrane anchoring sequence of Herpesvirus. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., membrane anchoring sequence of Herpesvirus is not recited in the rejected claims. The claims simply recite a polypeptide having at least one epitope of Herpesvirus outer membrane protein. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants next argue that Sajto et al., does not test antigenicity *in vivo*. However, it is noted that the features upon which applicant relies, such as testing antigenicity *in vivo*, is not recited in the rejected claims. Even though, antigenicity testing is not recited in the claims, Sajto et al., teaches the expression with a recombinant virus of a polypeptide modified to such as extent

as to exhibit an antigenicity equivalent to that of any of the above polypeptides. Thus, Sajto et al., teaches antigenicity. Applicants state that at least a portion of the antigens separate from the cell membrane cause the phenomena of "secretion" which is an unexpected result, however, again it is noted that the features upon which applicant relies upon are not recited in the rejected claims. The claims simply recite a polypeptide having at least one epitope of Herpesvirus outer membrane protein. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to use the polypeptide derived from Yoshida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Sajto et al., (WO 94/23019) because Sajto et al., teaches that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response.

Finally, applicant argues that Sajto et al., is directed to other fusion proteins and not the ones recited by the claims. However, the claims use "comprising" language which is open language. Further, as stated in the 112 1st rejections, the claims lack adequate written description by not reciting a specific fusion protein. There is no adequate written description of the fusion protein, or polypeptides comprising epitopes which requires a precise definition of the epitopes, polypeptides and fusion protein.

15. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) in further view of Yangida et al., is maintained. Applicants argue that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Sajto et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) have been discussed above. Yangida et al., teaches recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. Thus, it would have been obvious at the time of applicants invention to use the recombinant Avipox virus with exogenous DNA as taught by Yangida et al, with the fusion polypeptide of Yoshida et al., (Virology 1994 Vol. 200) and Sajto et al., (WO 94/23019)

because Yangida et al., teaches that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

April 26, 2001

4/30/01

JENNIFER E. GRASER
PRIMARY EXAMINER